REMARKS

Claims 46-91 are pending, and claims 46-48, 70, 74, and 90, which read on the species selected by the Office, are currently under examination. Claims 46-48 and 70 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Shiraishi et al., U.S. Patent Publication No. 2004/0087511 ("Shiraishi"), which is cited as a translation of PCT Publication No. WO 2002/062829. Claims 74 and 90 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Shiraishi in view of Akers, *Journal of Pharmaceutical Sciences*, 91:2283-2300, 2002 ("Akers").

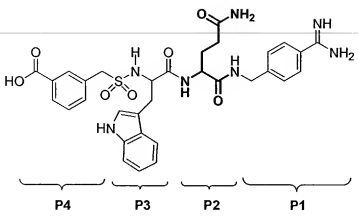
Claim Amendments

Claim 46 is currently amended to delete glutamine (Gln) is an allowed amino acid for P2. Claim 46 is further amended to recite the allowed amino acids for P2 when a linker is coupled to that group. Support for this amendment is found, for example, in the specification at page 18, lines 1-16, page 19, lines 4-13, page 20, lines 8-9, page 21, line 5, page 24, lines 6-13. Claim 48 is currently amended to delete hydrogen as a substituent group. Claim 53 has been amended to no longer recite "R_3." Claim 63 is currently amended to delete Gly, Ala, Gln, and Ser as allowed groups for Aaa. Lastly, claim 64 is amended to delete Gln as an allowed group for Aaa and to delete the phrase "or, when Aaa is Gly or Ala, R is HOOC-."

Applicants reserve the right to pursue the deleted subject matter in one or more continuing applications. No new matter is added by these amendments.

Claim Rejection under 35 U.S.C. § 102(b)

Claims 46-48 and 70 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Shiraishi. The Office asserts that Shiraishi teaches a method for inhibiting activity against blood coagulation factor VIIa where the peptide could be Compound A, which has the following structure:

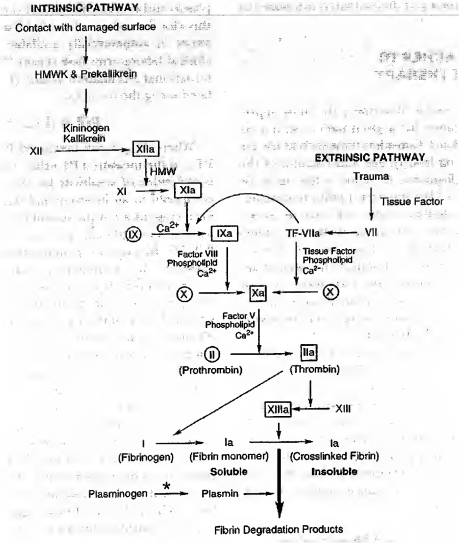


("Compound A").

Currently amended claim 46 does not encompass the highlighted glutamine residue of Compound A as an allowed group for P2. Accordingly, Compound A does not fall within the instantly claimed genus and cannot anticipate any of claims 46-48 or 70. Applicants request that this ground for rejection be withdrawn.

For the record, Applicants further disagree with the Office's assertion that the "claimed limitation 'inhibiting plasma kallikrein and/or factor XIa and/or factor XIIa' will necessarily be present in the method described by Shiraishi, since the same compound (Compound A) is administered to the same population" (page 7 of the Office Action). Initiation of the coagulation cascade can occur via two separate pathways: the extrinsic pathway and the intrinsic pathway (see, e.g., Shiraishi, paragraph [0003]). These two pathways are shown in the following schematic of the coagulation cascade.[1]

[1] Figure adapted from Williams et al., *Foye's Principles of Medicinal Chemistry, Fifth Edition*. Philadelphia: Lipppincott Williams & Wilkins, 2002, page 605.



As acknowledged by the Office, the Shiraishi compounds are inhibitors of factor VIIa, which is active in the extrinsic pathway. By contrast, the instantly claimed compounds inhibit enzymes (e.g., plasma kallikrein) that are active in the intrinsic pathway (see, e.g., page 2, lines 33-39, of the instant specification). Shiraishi explicitly teaches that "an inhibitor against factor VIIa will not affect the intrinsic coagulation pathway" (paragraph [0008]; emphasis added). This statement is consistent with the teachings of the instant specification: "an inhibitor of thrombin and [factor] Xa, or an inhibitor of [factor] VIIa as a specific inhibitor of the extrinsic coagulation cascade, does not have any inhibitory effect on the activation of the intrinsic coagulation cascade" (page 3, lines 22-27).

Accordingly, there is no factual basis for the Office's assertion that inhibitors of factor VIIa would inhibit any of plasma kallikrein, factor XIa, or factor XIIa.

Claim Rejection under 35 U.S.C. § 103(a)

Claims 74 and 90 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Shiraishi in view of Akers. The Office asserts that Shiraishi teaches all of the limitations of claims 74 and 90, except for the form of administration, and that this deficiency is remedied by Akers. Claim 74 depends from claim 46, and claim 90 depends from claim 74. As shown herein, Shiraishi does not teach the structural features of the compounds recited in instant claim 46, and this deficiency is not remedied by Akers. Accordingly, the combination of Shiraishi and Akers cannot teach or suggest all limitations of the current claims, and this ground for rejection should be withdrawn.

CONCLUSION

Applicants submit that the claims are in condition for allowance, and such action is respectfully requested. Applicants also respectfully request that claims 49-58, 60-62, 66-69, 71-73, and 75-89 be examined in accordance with M.P.E.P. § 803.02.

Enclosed is a Petition to extend the period for replying to the final Office action for three months, to and including December 11, 2009, and payment of the required extension fee.

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: 09 December 2009

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